

### **REMARKS**

Claims 1-46 and 48-53 are pending in the application. Claim 47 is canceled. Claim 41 has been amended herein to correct typographical errors. Therefore, claims 1-46 and 48-53 are pending and at issue. Applicants respectfully request reconsideration and allowance in light of the foregoing amendments and the following remarks herein.

As an initial matter, Applicants would like to thank Examiners Lauritzen and Casler for participating in the phone Interview held on July 5, 2011, to discuss the present application. During the Interview, Applicants discussed the significant technological differences between the present application and claims and the cited art. A brief summary of those differences will be presented below for the Examiner's convenience.

#### **The Present Application**

As discussed during the Interview, the present application is directed to methods and apparatus for screening or diagnosing cancer, such as breast cancer. Generally, a microwave source directs a microwave waveform to the patient's breast and a receiver receives the reflected microwave energy from the breast. This technology is generally analogous to radar imaging whereby the reflected energy is measured to image objects and locations of objects.

#### **The Cited Art**

The cited art, on the other hand, is directed to entirely different technologies. For example, as previously noted, Carr is directed to a method of detection that attempts to determine the differences in natural emitted radiation of normal tissue with that of cancerous tissue. Carr does not function similarly to a radar whereby reflected energy is received, but instead it is a passive system whereby the natural emission from the patient's breast is received.

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In fact, the passive nature of Carr oftentimes may lead to inaccurate or otherwise unreliable information due to normal differences of tissue radiation. Moreover, no useful information can be determined from the pattern of radiation from a single breast using the system of Carr. Such a method using natural emitted radiation of tissue is frequently tainted from background noise radiation from the tissue and because different patients emit different natural radiation. Observation of the patient's second breast is required to determine if radiation variations in the first breast are normal for the individual. An image using this method cannot be developed from variations in microwave radiation from a single breast thus limiting the technique to persons with two breasts to determine an abnormality in one breast distinct from an abnormality in the other breast.

Gleman is also directed to an entirely different form of technology. As discussed throughout Gleman, the technology involved is more akin to x-ray imaging as opposed to a radar type system. Gleman exclusively discusses having a transmitter on one side of an object and a receiver on the other side of the object to receive non-reflected portions from the transmitter. This is opposite the present application whereby reflected energy is received to image the object.

During the Interview, Examiner Casler inquired as to the technology and application discussed at Paragraphs 0066-0067 in Gleman as the phrase "Doppler imager" is used therein. Applicants believe that these paragraphs in Gleman also fail to disclose, suggest or enable the use of reflected energy for breast cancer screening and diagnosis. While Paragraph 0066 does use the term Doppler imager, Applicants believe the paragraph is still referring to non-reflected energy that is passed through an object as it interacts with other phenomena in the object. The imager could be used to analyze time variations or oscillations of energy as it passes through the object such that the energy is non-reflected energy.

Further, Paragraph 0067 also specifically discusses waves transmitted through the object under test. Gleman does use the term "reflected" in Paragraph 0067, but again, this is in

reference to sonic or ultrasonic waves passed through the object under test. Applicants believe Gleman was simply referring to the types of interactions and that the system may be able to determine that energy has been reflected and not necessarily capable of measuring the amount of reflected energy or be able to produce an image from the reflected energy. Additionally, all of the figures in Gleman are explicitly directed to receiving non-reflected energy passed through an object. Therefore, Applicants believe that Gleman is exclusively directed to receiving non-reflected energy that is passed through an object and/or would otherwise fail to enable imaging an object using reflected energy.

***Claim Rejections – 35 U.S.C. § 112***

Claims 1-46 and 48-53 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. More specifically, the Office Action alleges that the phrase “a predefined microwave waveform” is not defined. This rejection should be withdrawn as one skilled in the art would readily understand the phrase in view of the disclosure in the present application.

At various points in the detailed description, Applicants identify a number of features and characteristics of RF signals that may be used in the present application. For example, Paragraphs 40 and 43 identify exemplary frequency ranges that may be used in the present application. Additionally, Paragraphs 45 and 47 acknowledge that the waveform is known or otherwise predefined such that differences in phases or amplitudes of the frequencies in the reflected waveform from the known transmitted waveform can be used to identify the air gaps and changes in the dielectric properties of the object or objects causing the waveform to be reflected. Therefore, one skilled would readily understand the phrase “a predefined microwave waveform” from the present application.

The Office Action also notes that claim 41 states reflected energy is used from each breast independently and that such a statement cannot be inferred from the application.

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Applicants respectfully disagree. Throughout the present application, Applicants note numerous instances where the singular “breast” is scanned as well as a patient’s plural “breasts” are scanned. For example, comparing Paragraphs 18 and 19 of the present application, Paragraph 18 identifies “scanning the breast” (singular) while Paragraph 19 identifies “a pair of breasts being imaged.” Therefore, it would be readily understood by those skilled in the art that each of a patient’s breasts may be scanned and imaged independently or together such that this rejection should be withdrawn.

***Claim Rejections – 35 U.S.C. § 103***

Claims 1, 2, 6, 7, 9, 10, 17-20, 21, 24-38, 41-46, and 49-53 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gleman U.S. Patent Publication 2005/0251018 (“Gleman”) in view of Carr U.S. Patent 5,983,124 (“Carr”). This rejection should be withdrawn as the cited references fail to disclose or suggest one or more features recited in the present claims.

As noted above, the present claims are directed to an entirely different technology than the technologies described in either Carr or Gleman. Independent claim 1 recites a microwave assembly for directing a predefined waveform to the breast and receiving reflected microwave energy from the breast under examination resulting from the predefined microwave waveform (the remaining independent claims recite similar features). Carr simply fails to disclose or suggest these features, and, in fact, is directed to an entirely different form of technology which does not use reflected microwave energy. Instead, as discussed above, Carr is detecting the noise and weak signals emitted from the patient without any additional microwave waveforms being directed to the patient which may be reflected to aid in detection.

The claims also recite detecting the reflected microwave energy that results from the predefined microwave waveform that is directed to the patient. As Carr fails to direct any predefined microwave waveforms into the patient, it obviously cannot receive the reflected

microwave energy that results from the predefined microwave waveforms that are directed into the patient.

Gleman also fails to detect the reflected microwave energy that results from the predefined microwave waveform that is directed to the patient. As discussed above, Gleman is instead directed exclusively to detecting non-reflected energy that passes through an object. Independent claims 28, 41, and 46 recite similar features. Therefore, for at least these reasons, the rejections of the claims should be withdrawn.

Independent claim 41 further recites generating a 3D generated scan image of the breasts using reflected microwave energy from each breast independently resulting from the predefined microwave waveform. Carr simply fails to disclose such features, and in fact, teaches away from such features. As discussed throughout Carr, based on the type of technology used, it is required that the patient's breasts are compared to create any usable information. For example, in the Summary of Invention in Carr, the reference specifically states that it makes a temperature comparison at corresponding locations on the patient's breasts. This comparison is required to help decipher between the weak signals and the noise detected. Therefore, if a patient has already had one breast removed, Carr's system would be useless as there would be no baseline for comparison of the detected weak signals and noise. For this additional reason, the rejection of claim 41 should be withdrawn.

As discussed above, claim 41 also recites generating a 3D generated scan image of the breasts using reflected microwave energy from each breast independently resulting from the predefined microwave waveform. Carr is incapable of generating such a 3D image. Specifically, as discussed above, Carr is directed to a passive system for detecting weak energy and noise emitted from a patient's breast. These signals can only be detected as they are emitted from the surface of the breast. There is no teaching or suggestion that such signals could be detected subcutaneously to generate data for a 3D image. Therefore, for this additional reason, this rejection of claim 41 should be withdrawn.

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Claims 3-5, 8, 21, and 22 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gleman and Carr, as applied to claim 2, further in view of Meaney et al. U.S. Patent Publication 2004/0077943 ("Meaney et al."). This rejection should also be withdrawn as the cited references fail to disclose or suggest one or more features recited in the claims. As discussed above, Carr and Gleman fail to disclose or suggest one or more features recited in the present claims. Meaney et al. adds nothing regarding these deficiencies. Therefore, this rejection should be withdrawn and the claims allowed.

Claims 11, 12, 13-16, and 39-40 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gleman and Carr, further in view of Haddad et al. U.S. Patent 6,454,711 ("Haddad et al."). This rejection should also be withdrawn as the cited references fail to disclose or suggest one or more features recited in the claims. As discussed above, Carr and Gleman fail to disclose or suggest one or more features recited in the present claims. Haddad et al. adds nothing regarding these deficiencies. Therefore, this rejection should be withdrawn and the claims allowed.

Claims 23 and 48 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gleman in view of Carr, further in view of Horton et al. U.S. Patent 5,168,514 ("Horton et al."). This rejection should also be withdrawn as the cited references fail to disclose or suggest one or more features recited in the claims. As discussed above, Carr and Gleman fail to disclose or suggest one or more features recited in the present claims. Horton et al. adds nothing regarding these deficiencies. Therefore, this rejection should be withdrawn and the claims allowed.

Applicants respectfully request entry of the present amendment, reconsideration and withdrawal of the rejections to claims 1-46 and 48-53, and allowance of this application.

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The Commissioner is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,  
FITCH, EVEN, TABIN & FLANNERY

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